

## REMARKS / ARGUMENTS

### Election / Restriction

In view of the requirement for restriction, an election has been made to prosecute claims directed to the invention of Group I. This invention has been identified as that embraced by claims 1-14, to the extent directed to compounds of formula I wherein  $R^2$  and  $R^3$  form a ring according to formula II and wherein q is 1, r is 1 and  $Y^1$  is a nitrogen atom. The invention of Group I has been defined as also including pharmaceutical compositions and method for the treatment of headache, including migraine or cluster headaches, classified in various subclasses of 544.

The claims have been amended so that they are now directed to only elected subject matter. Claims 15 and 16, which had been withdrawn from consideration have been canceled.

### Double Patenting

Claim 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/755593.

It is noted that this application was filed on October 15, 2003 whereas copending Application No. 10/755593 was filed on January 12, 2004. Thus the present application is the earlier of the two. It is requested that the provisional rejection be maintained in the present application until there are no other rejections remaining. Then, it is requested that the rejection be withdrawn, in the manner described by MPEP Section 804.

### Claim Rejections – 35 USC § 102

Claims 1-9 and 12-14 are rejected under 35 USC 102(b) as being anticipated by Klaus et al. (US 6,344,449). The action asserts (with reference to an STN printout) that Klaus et al. teach the compounds of the instant invention where  $R^1$  is 2-oxoquinazolinyl, A is Oxygen, X is NH, U and W are  $CF_3$ , V is Hydrogen,  $R^5$  is Hydrogen,  $R^2$  and  $R^3$  form a ring, of formula II, and  $R^4$  is 1-methylpiperidin-4-yl.

Before directly addressing the rejection, the Applicants wish to point out that formula I in Claim 1 has been amended. In Claim 1 in the application as filed, formula I was depicted as including a phenyl ring which is substituted in the 3, 4 and 5-positions by U, V and W, respectively. This depiction of formula I is incorrect and is due to a typographical error. The correct depiction of formula I is given in the specification at page 1, lines 11-13. Thus, the amendment will not introduce new matter. It can be seen that in the correct depiction of formula I the phenyl ring is substituted in the 3 and 4-positions by Y and Z, respectively. The remaining positions of the phenyl ring are unsubstituted. Claim 1 has been amended so that the depiction of formula I in the claim is the same as the depiction of formula I in the specification.

Attention is next directed to the definitions of Y and Z given in claim 1. Claim 1 states: "Y and Z independently of one another each denote a straight-chain or branched C<sub>1-6</sub>-alkyl group wherein each methylene group may be substituted by up to 2 fluorine atoms and each methyl group may be substituted by up to 3 fluorine atoms". Thus, the phenyl ring in question is necessarily disubstituted, in positions 3 and 4 by alkyl groups, and these alkyl groups may be fluorinated.

The STN search report mentioned by the Examiner shows 7 compounds that are described by the cited US 6,344,449. None of these 7 compounds contains a phenyl moiety that is disubstituted, in positions 3 and 4 (by Y and Z), as required by the claims. Thus, none of these y prior art compounds anticipates the claims, as amended.

To sum up, entry of the amendments will correct the error in formula I in the claims and there will then be no anticipation by the '449 patent.

Claim Rejections – 35 USC § 103

Claims 1-14 are rejected under 35 USC 103 as being unpatentable over Klaus et al. (US 6,344,449).

The rejection of the claims is respectfully traversed. It is conceded that a prima facie case of obviousness has been established. Nevertheless, it is asserted that the claims in the present application are directed to a selection invention that falls within the generic scope of the '449 but which selection is not made obvious by the disclosure of the '449 patent. The Applicants stand ready to show by way of comparative test data (to be presented in a Rule 132 declaration) that compounds of the present selection invention are unexpectedly, significantly more potent (have significantly lower IC<sub>50</sub> values) than do the closest species exemplified by the '449 patent.

Claim Rejections – 35 USC § 112

1. Claim 14 is rejected under 35 USC 112, first paragraph. The action states that the instant specification does not enable the use of the compounds of formula I for the prevention of all kinds of headaches without undue experimentation.

To overcome this basis of rejection Claim 14 has been amended so as to be limited to the treatment or prophylaxis of just migraine or cluster headaches.

It is apparent that the rejection is also due in part to a belief on the part of the Examiner that migraine and cluster headaches are not amenable to prophylaxis. To this extent the rejection is traversed. It should be noted that the prophylaxis or reduction in the frequency of migraine or cluster headache by medication is quite well established in the medical literature. See for example the discussion concerning preventive medications at <http://www.mayoclinic.com/health/migraine-headache/DS00120/DSECTION=8>. There is no reason to suppose that the compounds of formula I can not be used for prevention or prophylaxis in the same manner (dosage) that they are to be used for treatment.

2. Claims 1-14 stand rejected under 35 USC 112, second paragraph.

The rejection is due in part to the fact that formula I is depicted incorrectly in Claim 1, as previously noted. The basis for the rejection should be overcome, in part, by the amendment of claim 1 which corrects the depiction of formula I, as previously discussed. Claims containing the limitations Y and Z are not indefinite once formula I is correctly depicted in claim 1.

The rejection is also based upon the assertion that the term imino group connotes a carbon atom double bonded to a nitrogen atom whereas the examples show that the moiety X is a nitrogen atom, not a carbon atom double bonded to a nitrogen. Applicants traverse the rejection on this basis. Applicants do not agree with the Examiner's overly restrictive definition for the term imino group. The term can connote any bivalent NH group. The two valences can bond with a single carbon (the kind of imino group the Examiner has in mind) or they can bond with two different carbon atoms (the kind of imino group that the Applicants have in mind with regard to the moiety X).

Application No. 10/685,921  
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3. Finally, Claims 1-14 stand rejected under 35 USC 112, second paragraph, because it is asserted that the definition of R<sup>4</sup> in claim 1 is ambiguous. The Examiner asks, "Does the limitations in the passage spanning page 216 line 21 to page 218 line 9 apply to all Y<sup>1</sup>s or only in the case of Y<sup>1</sup> equal to carbon?"

This basis for rejection is overcome by the amendments made in the claims. Thus, the definition of Y<sup>1</sup> has been limited to a nitrogen atom. This makes the following passage superfluous:

or, if Y<sup>1</sup> does not denote the nitrogen atom, the carboxy, aminomethyl,  
alkylaminomethyl or dialkylaminomethyl group,

The passage has accordingly been removed by amendment, curing the indefiniteness complained of.

Respectfully submitted,  
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